



OBBR

Office of Biorepositories
and Biospecimen Research

Research & Policy Initiatives in NCI's Office of Biorepositories & Biospecimen Research

Translational Research Interest Group

December 10, 2009

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Deputy Director

Office of Biorepositories & Biospecimen Research

National Cancer Institute, NIH, DHHS





Inside Huntsman Cancer Institute's vaults: Pancreatic tumors on ice. Lance W. Clayton for TIME

Folks at the National Cancer Institute (NCI) are heading up an effort to establish the U.S.'s first national biobank — a safe house for tissue samples, tumor cells, DNA and, yes, even blood — that would be used for research into new treatments for diseases.... By fall, the group hopes to have mapped out a plan for a national biobank; the recent stimulus showered on the government by the Obama Administration might even accelerate that timetable.

Translational Research Promises to Realize the Vision of Personalized Medicine

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Molecular Data

Diagnosis / Therapy

Translational Research

PERSONALIZED CANCER CARE

Biospecimen Analysis

Biospecimen Collection

Biospecimen Processing and Banking



Towards a National Biospecimen Resource: A Step-Wise Process

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2009

- OBBR begins detailed strategic planning process for caHUB (first working group meeting held June 17, 2009)

2008

- OBBR studies market demands; risk/benefits; organizational and funding models

2007

- NCI Director asks OBBR to explore plans for a national biospecimen resource

2006

- OBBR publishes the NCI Best Practices for Biospecimen Resources

2005

- Biospecimen Research Network (BRN) is formed

2003

- OBBR is formed

2002

- National Biospecimen Network (NBN) Blueprint published

- National Dialogue on Cancer identifies biospecimens as critically important to post-genomic research



The USA Lags Behind Other National Initiatives

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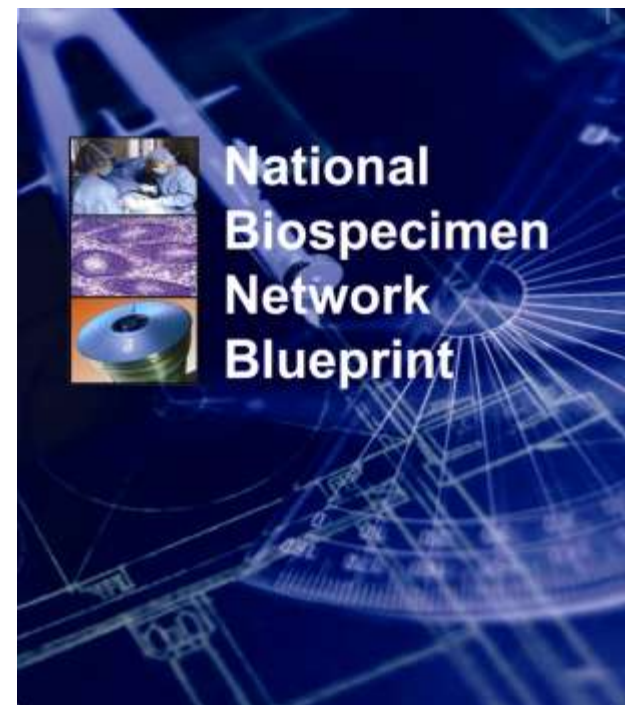
- ***Iceland DeCode Biobank***
 - National; Population-based
- ***Estonian Genome Project***
 - National; Population-based
- ***UK Biobank***
 - National; Population-based; Ages 45-69
- ***GenomEUtwin (Finland)***
 - International; Population-based; Twin cohorts
- ***Biobanking and Biomolecular Resources Research Infrastructure***
 - Pan-European; Network of new and existing biobanks (population, twin, case/control)
- ***Biobank Japan***
 - National; Hospital patient-based;
 - Focus on common diseases and pharmacogenomic research
- ***OnCore UK***
 - National; Cancer Tissue and Blood Repository for research
- ***Singapore Tissue Network***
 - National; Tissue and DNA Bank for translational and population research for Singapore
 - Collects, processes, and disseminates tissue samples for specific research projects

National Biospecimen Network Blueprint

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Key principles for a national biobank:

- Standardized biospecimen collection and distribution procedures
- Standardized data sets and data vocabulary
- Harmonized approach to ethical and legal issues
- Standardized consent, MTAs
- Transparent governance and business models
- Transparent access policies
- Large well-designed specimen sets for a variety of research questions





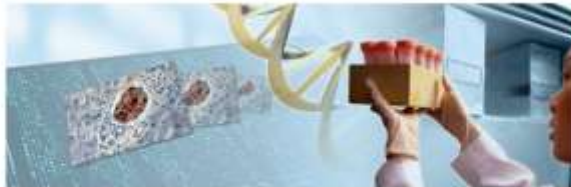
National Biospecimen Network Pilot Study

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- Carried out in 2005-2006 among 11 prostate cancer SPORE sites around an inter-SPORE biomarker project in prostate biopsies
- Challenges posed by process variation among study sites:
 - Different procedures for collecting tissues
 - Different procedures for obtaining informed consent
 - Different informatics systems that were not interoperable
 - Lack of information necessary to identify sources of variation
 - Lack of ability/authority of participants to institute procedural changes within their institutions that would be needed to harmonize across sites
- Pilot terminated
- “Rule book” needed: *NCI’s Best Practices for Biospecimen Resources*
- “Business model” inadequate: academic, collegial, bottom-up

NCI Best Practices for Biospecimen Resources

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National Cancer Institute Best Practices for Biospecimen Resources

June 2007

Prepared by:
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services

Objectives:

- Unify policies and procedures for NCI-supported biospecimen resources for cancer research
- Provide a baseline for operating standards on which to build as the state of the science evolves
- **Being updated in early 2010**

<http://biospecimens.cancer.gov>



NCI Best Practices Overview

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The NCI Best Practices include recommendations for:

- **Common technical, operational and safety best practices**
- **Quality assurance and quality control programs**
- **Implementation of enabling informatics systems**
- **Establishing reporting mechanisms**
- **Providing administration and management structure**
- **Addressing ethical, legal, and policy issues: informed consent; access; privacy protection; custodianship; intellectual property**



Case Study from The Cancer Genome Atlas (TCGA): Biospecimen Challenges and Solutions

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- Large-scale team project to explore the full spectrum of cancer-associated genomic changes: coordinated, comprehensive approach
 - Data made available to the broad research community
 - Pilot phase 2006-2009
- Premise: Cancer is a disease of genomic alteration
 - Many alterations remain unknown
- Envisioned benefits (underpinnings for personalized medicine):
 - Elucidate etiologies
 - Provide bases for molecular classification, taxonomy
 - Reveal targets for therapy
 - Provide insights into clinical behavior; prediction, prognosis



Case Study from The Cancer Genome Atlas (TCGA): Biospecimen Challenges and Solutions

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TCGA pilot project

- Three different cancers: brain, ovarian and lung
- Biospecimens obtained from a network of retrospective collections at multiple academic medical centers
- Centralized pathology and molecular QC of samples (caHUB model)
- Molecular analyses – 10 platforms
 - RNA and micro-RNA profiling
 - Copy number variation
 - Translocation analysis
 - Epigenetic (methylation) analysis
 - Sequencing
- Clinical data collected for clinical correlation



TCGA Specimen Requirements

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- Set by the technical demands of the molecular analysis platforms
- All 10 analysis centers would analyze exactly the same molecules from the same samples from the same patient - all data directly comparable
 - Sufficient quantity to satisfy all platforms
 - Sufficient quality to yield interpretable data on all platforms
- The target number of 500 cases per tumor type: defined depth of analysis and probability of finding genomic changes that occur infrequently (3% level)



TCGA Lessons Learned - Real Numbers

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- From responses to original Request For Information (RFI) in 2006, estimated that all 1500 cases could be acquired from 4-6 sites
- TCGA now working with >50 sites (and counting)
 - Several are outside the USA
- Impossible to reach accrual goals from retrospective collections alone
- Prospective collection instituted – relevant to caHUB planning



TCGA Lessons Learned - Real Numbers

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- Biobank inventory drop-out rates as high as 95 – 99%
- Molecular QC failure rates for qualifying samples typically 30%

	Repository 1 (Major Academic Site)	Repository 2 (Major Academic Site)
# Frozen samples logged in collection	5000+	1200+
# Samples meeting spec upon detailed review of inventory	1392	120
# Samples meeting physical/pathological specs	174	18

Before full
pathology
review



Case Study from The Cancer Genome Atlas (TCGA): Biospecimen Challenges and Solutions

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- **Quality of existing samples is typically overestimated by biobanks**
- **Collection of normal control samples is not routine**
- **Histological quality does not guarantee molecular quality**
- **Other important factors:**
 - **Consent, IRB, HIPAA issues**
 - **Material Transfer Agreement, Intellectual Property, Authorship, Incentives issues**
 - **Governance and communication challenges**
 - **Informatics needs**
 - **Extraction and transfer of associated clinical data**
 - **Standards compliance (caBIG™)**
 - **Costs**



TCGA as a Pilot for a National Biobank - Specimen Collection and Processing

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Prospective patient consent and tissue collection instituted:

- Protocols designed to maximum qualification of samples
 - Handling appropriate for specimen type and study design
- Protocols started at the source
 - Surgical /OR staff, consent
- Learned that Standard Operating Procedures, training and education required for all aspects



Lessons Learned from TCGA - Top 5 Sources of Glioblastoma Failure

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- Matched normal germline DNA controls (blood or other) lacking
- Insufficient tumor cellularity in samples
 - Tumor cellular composition too low
 - % necrosis too high
- Specimen size too small
 - Insufficient for minimum required DNA/RNA for all analyses
- Molecular quality insufficient
 - QC failure of DNA or RNA
 - Insufficient amount
- Clinical data incorrect: Tumor not primary disease
 - Samples derived from recurrent, i.e. previously treated GBMs (confounding issue: Rx-related effects)



Case Study from The Cancer Genome Atlas (TCGA): Biospecimen Challenges and Solutions

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- TCGA is now a proven success
- First Nature paper published October 2008
 - Most comprehensive high-quality data set on GBM to date
- Recently approved by BSA for continuation/scale-up
- Specimen accrual recognized as the biggest challenge for the project
 - High-quality data dependent on high-quality analytes from high-quality specimens
 - Strong recommendation to adhere to specimen quality standards
- Bottom line: specimen challenges can be met and are worth the effort, but we don't already have what we need in our current system

Lessons learned/solutions developed directly applicable to caHUB



On the Road to Molecular Medicine...

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...There are some significant obstacles to progress

Lack of standardization of biospecimen collection, processing and storage:

- Needed in order to provide robust testing of patient samples
- Important to Clinical Work and R&D
- Lack of knowledge about how different methods of biospecimen collection, processing and storage alter the biological picture presented by the specimen
- A significant confounding factor in research



Multiple pre-analytical variables can affect the molecular integrity of the biospecimen

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Variables (examples):

- Antibiotics
- Other drugs
- Type of anesthesia
- Duration of anesthesia
- Arterial clamp time

Time 0

Variables (examples):

- Time at room temperature
- Temperature of room
- Type of fixative
- Time in fixative
- Rate of freezing
- Size of aliquots



Patient

Medical/
Surgical
Procedures

Acquisition

Handling/
Processing

Storage

Distribution

Scientific
Analysis

Restocking
Unused
Sample

Pre-acquisition

Post-acquisition



Pre- and Post- Acquisition Variables Impact Clinical and Research Outcomes

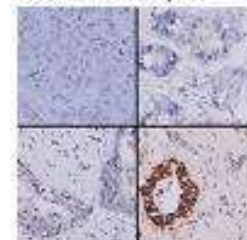
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– Effects on Clinical Outcomes

- **Potential for incorrect diagnosis**
 - Morphological/immunostaining artifact
 - Skewed clinical chemistry results
- **Potential for incorrect treatment**
 - Therapy linked to a diagnostic test on a biospecimen (e.g., HER2 in breast cancer)

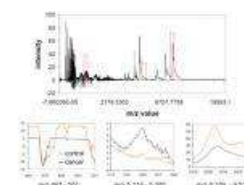
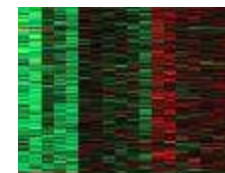


HER-2 as assessed by IHC



– Effects on Research Outcomes

- **Irreproducible results**
 - Variations in gene expression data
 - Variations in post-translational modification data



Misinterpretation of artifacts as biomarkers



Lack of Standardization

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Human biospecimens are collected, processed and stored:

- **In many different institutions**
- **With many different SOPs guiding the biospecimen workflow**
- **Sometimes without detailed SOPs that are strictly adhered to**

This can result in significant biological variation in biospecimens - that has nothing to do with disease!





NCI's OBBR: Building Better Biospecimen Resources

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**Developing and implementing
state-of-the-science processes that ensure
molecular integrity and clinical relevance
of human biospecimens used in
cancer research and clinical medicine**



OBBR's Systematic, Comprehensive Approach to Improving Biospecimen Quality

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- Help the US move toward standardized procedures for biospecimen collection, processing and storage: *The NCI Best Practices for Biospecimen Resources*
 - Appropriate patient informed consent
 - Encouraging the use of appropriate, standardized protocols and QA/QC procedures
 - Biospecimen data – patient clinical data, diagnostic data, biospecimen handling data (*maybe half the value of the specimen*)
- For more see: <http://biospecimens.cancer.gov>



OBBR's Systematic, Comprehensive Approach to Improving Biospecimen Quality

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- Work with NCI, NIH, other national and international groups on targeted programs in biobanking
 - The Cancer Genome Atlas
 - Clinical Proteomics Technologies Assessment for Cancer
 - National Community Cancer Centers Program
 - Interagency Oncology Task Force
 - NCI-FDA-AACR Biomarkers Collaborative
 - In the planning stages – a National Cancer Biobank, the caHUB.



OBBR's Systematic, Comprehensive Approach to Improving Biospecimen Quality

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- Sponsor, collaborate, and promote research on biospecimen science:

The Biospecimen Research Network



The Biospecimen Research Network: Supporting Collaborative Research

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- Provide a forum for research results on how biospecimen variables affect molecular analysis:
 - The Biospecimen Research Database: Make existing and emerging biospecimen research data more accessible
 - Annual symposium: “Advancing Cancer Research through Biospecimen Science” *March 24-25, 2009 Bethesda MD* <http://brnsymposium.com>
- Generate new research data:
 - New Extramural Research Programs
 - IMAT Program – “Innovative and Applied Emerging Technologies in Biospecimen Science” (RFA)
- Collaborate with other programs, e.g.:
 - Clinical Proteomics Technologies Assessment for Cancer (CPTAC)
 - The Cancer Genome Atlas (TCGA)



Research Contracts Awarded for RFP "R&D on Human Biospecimen Integrity"

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- University of California, San Francisco
PI: Katherine Williams, PhD
"Credentialing Plasma and Serum Biospecimen Banks for Proteomics Analysis"
- Yale University School of Medicine
PI: David L. Rimm, MD PhD
"Intrinsic Controls for Formalin Fixed, Paraffin Embedded Tissue"
- MD Anderson
PI: W. Fraser Symmans, MD
"Effects of Biospecimen Integrity, Intratumoral Heterogeneity, and Analytical Variance on Microarray-based Pharmacogenomic Tests of Breast Cancer"
- PPD
PI: Chris Becker, PhD
"Investigations into the Effects of Blood Specimen Handling Procedures on Protein Integrity"



More BRN RFPs

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- **"Biospecimen Contributing Institutions for Research Studies in Cancer Tissue Pre-Analytical Variables" was issued on May 5, 2009**
- **First component of a larger multi-center research project to fulfill this need.**
- **The BRN is anticipating awarding contracts in this area early in 2010.**
- **Additional RFPs covering other components of this project will be issued and awarded in 2010.**



The Momentum Increases: Requirement for a National Biospecimen Resource Is Widely Cited

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- **HHS *Personalized Health Care Report*, September 2007**

- Discusses NCI initiatives to advance personalized medicine “in which the principles of high-quality shared biospecimen resources are critical for achieving research goals”

- **IOM Report: *Cancer Biomarkers*, 2007**

- Recognizes importance of biospecimens; supports NCI’s guidelines and standards
- Supports principles of NBN concept

- **President’s Council of Advisors on Science and Technology:**

- Priorities for Personalized Medicine*, September 2008**

- Calls for the creation of a national network of standardized biospecimen repositories
- NCI efforts and OBBR guidelines (Best Practices) specifically cited

- **Kennedy-Hutchinson Cancer Bill (“War on Cancer, Part II”)**

- Proposal for a far-reaching comprehensive approach to addressing cancer
- OBBR input through advocates working with Senator Kennedy: NBN cited
- Expected to be introduced during this Congressional session

- **NCI’s “Bypass Budget”: *FY2010 Nation’s Investment in Cancer Research***

- Featured: OBBR and planning for a National Biospecimen Resource



What Is caHUB?

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A unique, non-profit public resource that will ensure the adequate and continuous supply of human biospecimens and associated data of measurable, high quality acquired within an ethical framework.

caHUB Strategic Planning Process

STEP 1: MARKET RESEARCH

Project Organization

- Initial management team
- Process expectations
- Key planning questions
- Guiding principles
- Initial assumptions
- Requirements for success

Market and Environmental Assessment

• Internal Capabilities

- Project, alliance management
- Scope and distribution of services
- Facilities, technology, capacity
- Operations and systems
- Organization and management
- Financial performance

• External Assessment

- Demographics
- Competition
- Demand
- Major trends (technology, research, etc.)
- Market perception
- Opportunities and threats

STEP 2: PROGRAM DESIGN

Program Direction and Strategies

- Future environmental assumptions
- Mission and vision
- Overall planning targets (goals)
- Measures of success
- Oversight and governance

Product and Service Development Plan

- Scope of product
- Scope of services
- Product acquisition model
- Disease/tissue targets
- Program development priorities
- Partnering needs
- Recruitment needs

STEP 3: BUSINESS AND IMPLEMENTATION PLANNING

Organizational Plan

- Partner/collaborator /researcher relationships
- Organization structure
- Program leadership
- Business development
- Ethics, legal, privacy, policy frameworks

Operational Assumptions

- Staffing
- Accessibility/policies
- Customer service
- Product acquisition oversight and management
- Program scale-up targets

Communications Plan

- Key messages
- Key stakeholder groups
- Plan roll-out/timing
- Marketing objectives and strategies
- Web site development

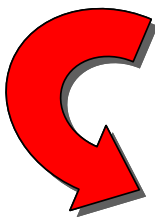
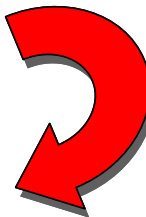
Financial Impact

- Capital investment
- Reimbursement models
- Operating *proforma* analysis
- ROI

Implementation Plan

- Milestones
- Actions
- Responsibilities
- Resource requirements
- Sequence/priority

Bioinformatics/IT Infrastructure





Preliminary Stakeholder Market Research

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Methods

Time Frame

Respondents

In-depth Interviews

July/August 2008

22 (30 invited)

Online Survey

October 2008

727 (~5000 invited)

Types of Respondents

- Academia (the majority)
- Federal agencies (NCI, NIH, other)
- Cancer/clinical centers
- Foundations and advocacy groups
- Industry (pharma, biotechnology)

Themes of Questions

- Need for quality biospecimens
- Barriers to access
- Consequences of poor access to quality specimens
- Response to the concept of a central biorepository resource



Key Survey Findings: Researchers Are Working in Silos

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What percentage of your biospecimens come from each of these sources?

	% Get any from source	Mean % from each
My patients/volunteers	42%	25%
Other patients in my org	55%	31%
Other research institutions	41%	17%
Other medical care facilities	23%	8%
Commercial U.S. biobank	18%	6%
Non-profit biobank	12%	4%
NCI CHTN	12%	4%
Sources outside the U.S.	4%	1%
Other sources	1%	1%

56%

- Collaborative agreements are not widespread**

55% None/Few (0-25%)

23% Some/Many (26-75%)

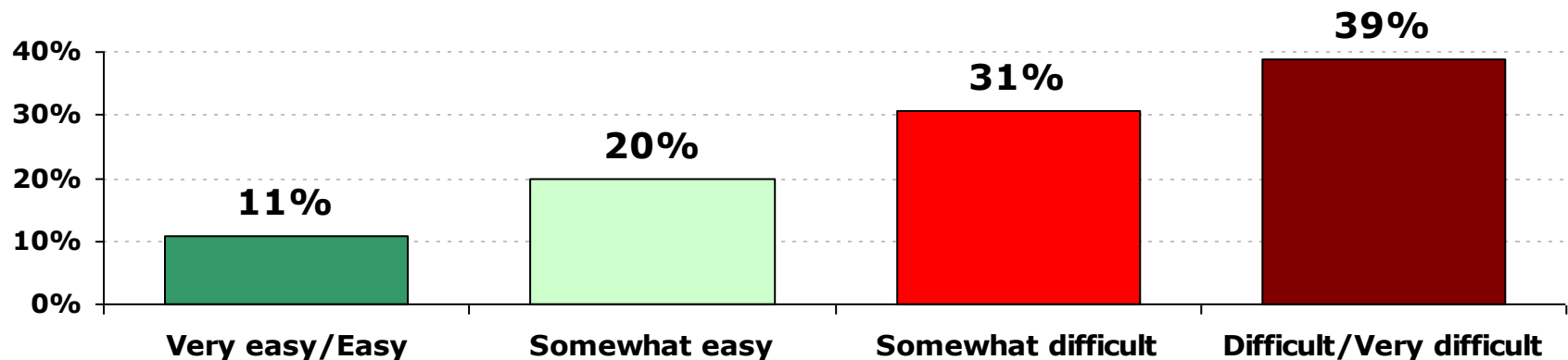
22% Most/All (76-100%)

What proportion of your biospecimens come from individuals or organizations who are your research collaborators?

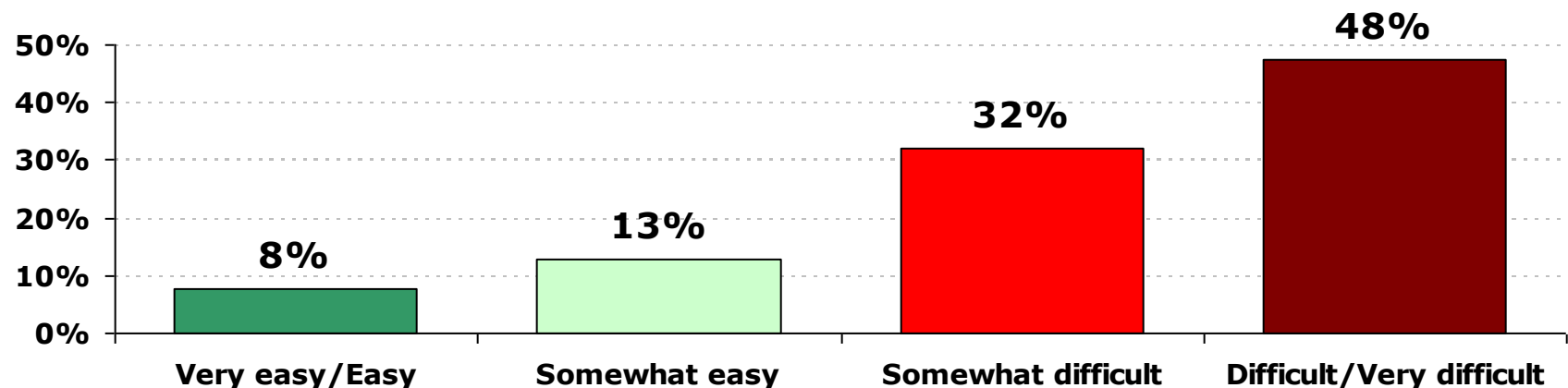
Silos Make It Hard for Researchers to Get What They Need

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Ease of Accessing the Quantity of Biospecimens Needed



Ease of Accessing "High Quality" Biospecimens

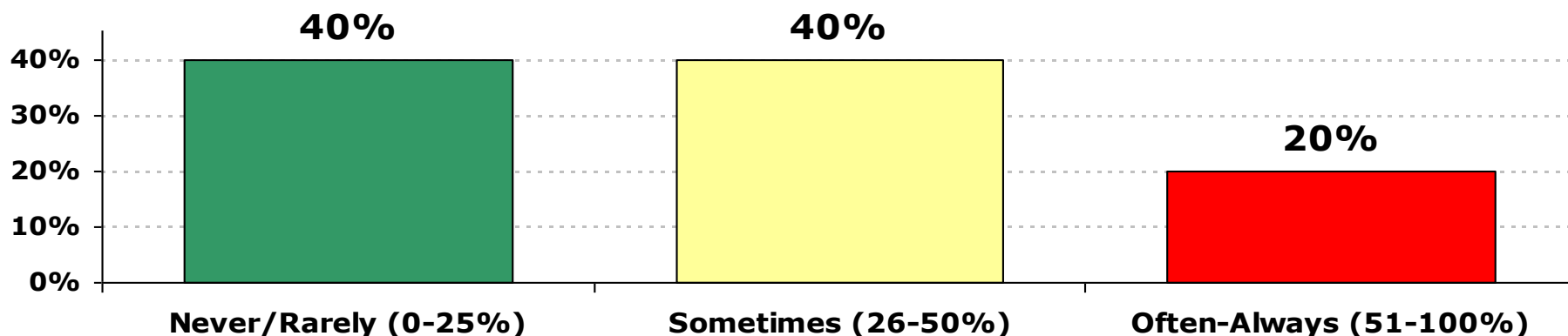




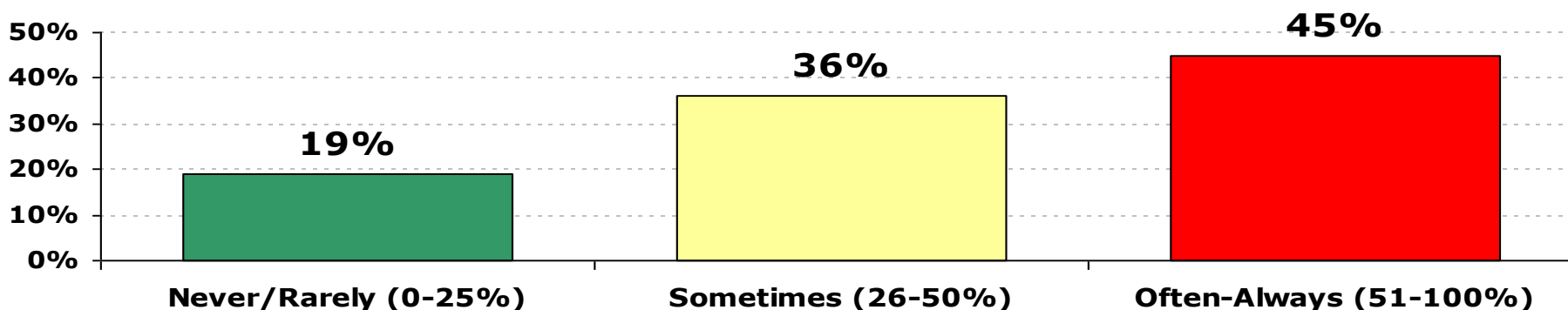
The Science Suffers: Consequences for Investigators

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Question Their Data Because of the Quality of Biospecimens

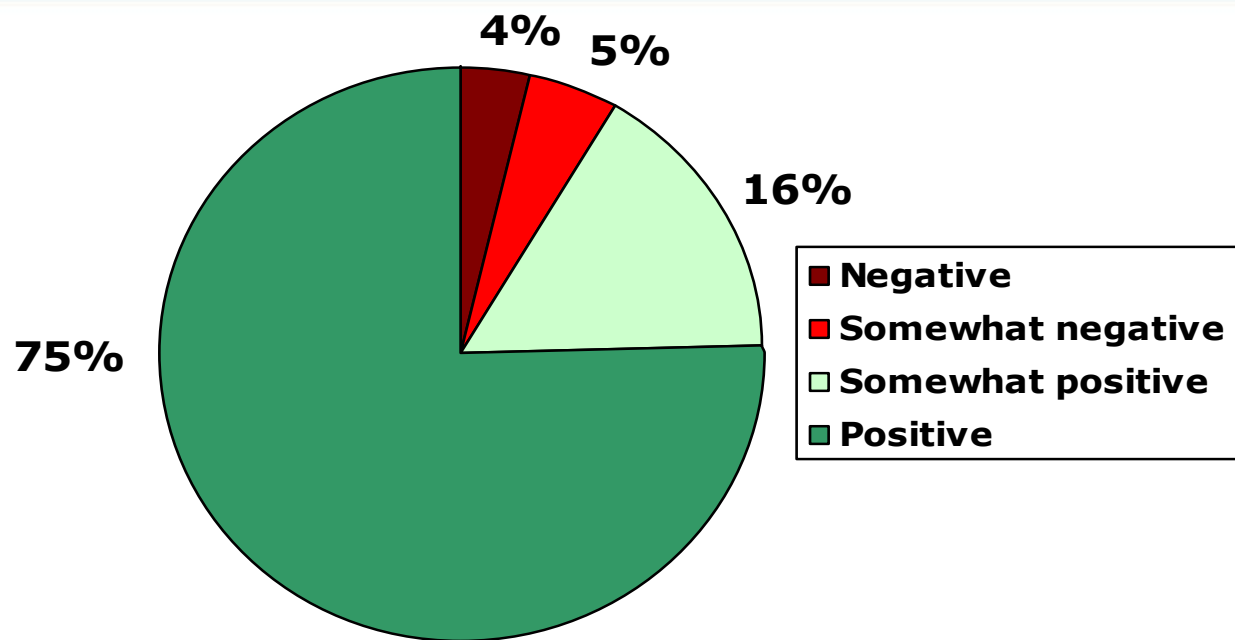


Limit Their Scope of Work Due to the Shortage of Quality Biospecimens



Reaction to a National Biobank

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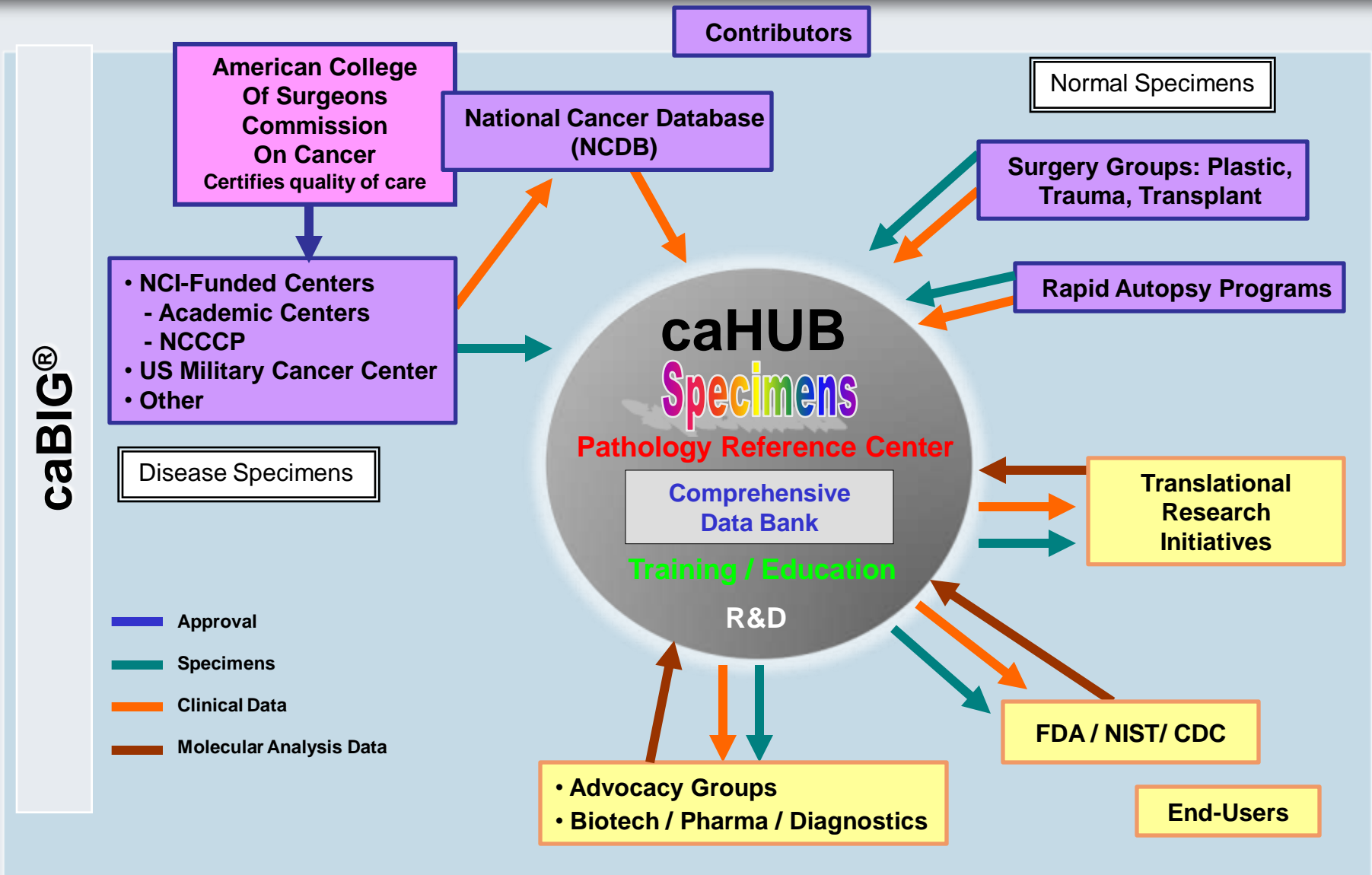
How likely would you be to obtain biospecimens from this repository?

62% Very likely
25% Somewhat likely
7% Somewhat unlikely
6% Very unlikely

How willing would you be to contribute biospecimens to it?

53% Very willing
31% Somewhat willing
11% Somewhat unwilling
5% Very unwilling

caHUB (Cancer Human Bio**b**ank)



caHUB: **UNIQUE** • **HIGH QUALITY SPECIMENS** • **HIGH QUALITY DATA** • FROM PTS WHO RECEIVED **HIGH QUALITY CARE**



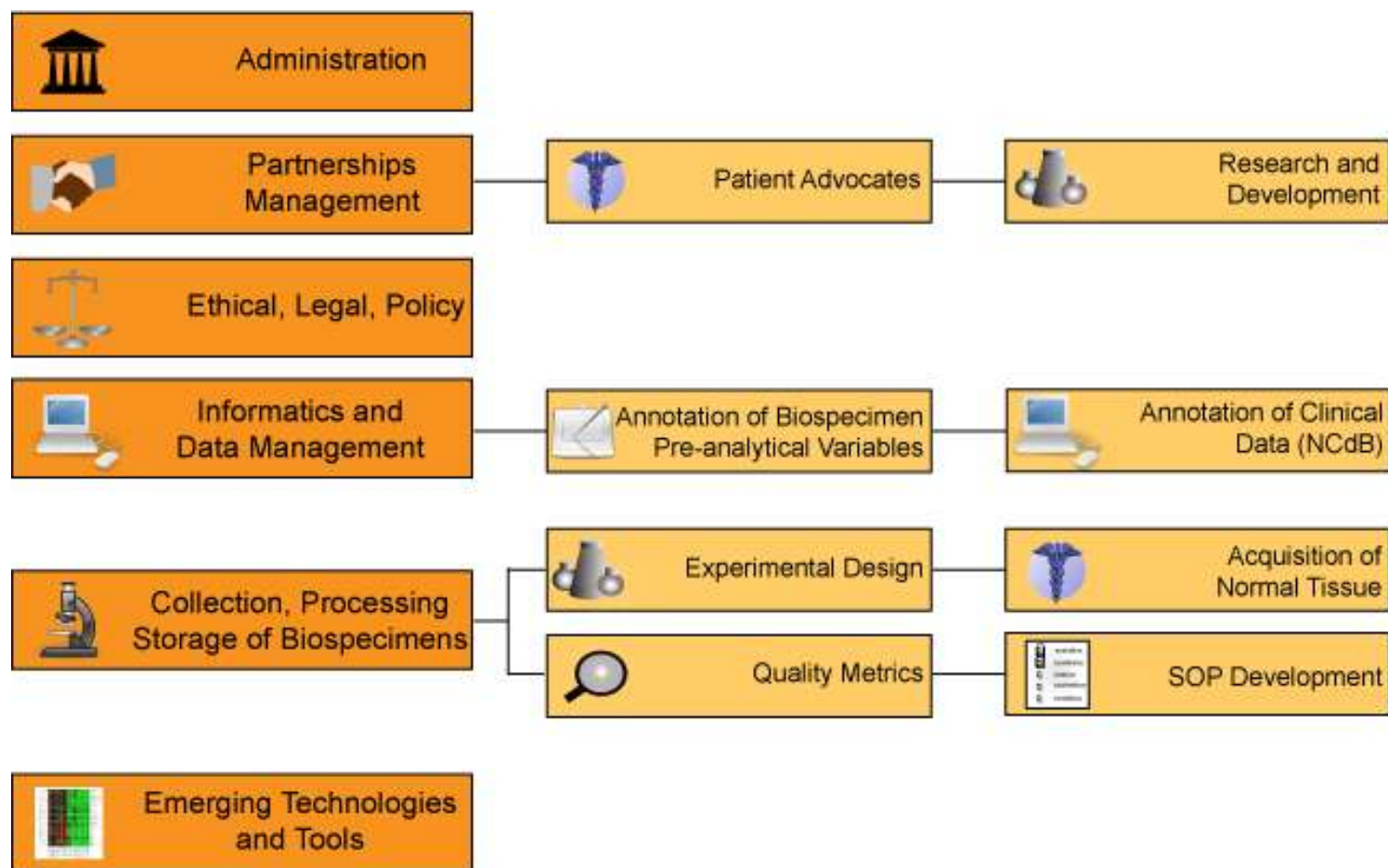
caHUB Key Concepts

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- **Scientifically designed collection strategies: multiple aliquots of every specimen**
- **Standardized, annotated collection, processing**
- **Pathology analysis of every specimen**
- **Uniquely rich, standardized data profile of each sample**
- **Provision of tools, resources, training for biospecimen resources throughout the country**
- **Centralized source of normal human specimens**
- **Source of standardized human samples for all stakeholders**
 - **Duplicate samples of same high-quality, specimens allow direct comparisons of data from different scientific initiatives / oncology product development steps**
 - **"Big science" can be linked through the specimens**
 - **Product (therapeutic; diagnostic) and technology development/standardization/regulatory approval streamlined**
 - **Direct product performance comparisons possible**
 - **Standardized reference specimens ("yardstick of truth") for FDA approval / medical implementation**
- **Unprecedented return on investment and rapid acceleration of scientific knowledge**

Working Groups to Support Development of Functional Areas

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Working Groups and Outputs

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- Establish through SAIC-Frederick (NCI Contractor)
- Membership to include internal and external stakeholders
- Specific content expertise in each functional area
- Task with specific missions and outputs
- Outputs to aid in caHUB development:
 - Funding and cost-recovery models
 - Ethical, legal, and social frameworks
 - Models for the Pathology Reference Center and quality control
 - Standard operating procedures
 - Partnerships management model
 - Models for informatics and data management



First Administration Working Group Meeting June 17, 2009

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Questions/Issues:

- How should caHUB be structured physically—a single biorepository/laboratory or a network of laboratories/biorepositories with a common informatics structure? Where should either the central or network structures be located?
- How does caHUB assure major tissue acquisition groups that it is not competitive, and how, in other instances, does it complement and synergize with existing biobanking initiatives?
- How does the NCI get buy-in from tissue sources (e.g., ensuring intellectual property rights and operational resource availability)?
- What do you think it will cost to create and operate caHUB? What approach should be followed to determine the cost structure?
- What funding and cost recovery models should govern caHUB activities? What other plans would not work as well and why?
- How long will it take before caHUB can sustain itself with public/private partnerships?



Sustainable Funding Models for caHUB

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- Consulting firm engaged to develop a cost-recovery, sustainable-funding model
- Public-private partnership envisioned following demonstration phase
 - OBBR working with NIH Public-Private Partnership Office
 - OBBR working with Foundation for the NIH (FNIH)
- Public-Private Partnership
 - Government and non-government (industry, advocacy, academic) represented
 - Governance/decision-making includes NCI, but not limited to NCI
 - NCI gives up some ownership (negotiated)



caHUB Goals: Accelerating the Vision of Personalized Medicine

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- Develop and widely disseminate evidence-based standard operating procedures
- Document and evaluate the current status and quality of human specimen inventories available for research through extensive market research
- Identify strengths in existing specimen demand-supply as well as identify areas of opportunity for further development
- Engage in contractual relationships with tissue source sites to acquire needed biospecimen types
- Support and sponsor research in biospecimen science to further refine and improve standard biobanking practices
- Support and sponsor innovative technology development in biobanking and integration of new and existing technologies into current biobanking practice
- Develop and disseminate tools and resources to support new and existing biospecimen resources
- Engage in public education, awareness activities, and support the development of training programs in biospecimen science

OBBR is...

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- Carolyn Compton, Director
- Jim Vaught
- Helen Moore
- Joyce Rogers
- Nicole Lockhart
- Kim Myers
- Mark Lim
- Richard Aragon
- Sherry Sawyer
- Priyanga Tuovinen, Pres Mgt Fellow
- Tony Dickherber, AAAS Fellow
- Sharon Collins
- SAIC-Frederick contract staff
- Consulting pathologist, surgeon, informatics and biobanking specialists



http://biospecimens.cancer.gov

Home Page - Office of Biorepositories and Biospecimen Research - Microsoft Internet Explorer

File Edit View Favorites Tools Help



Address http://biospecimens.cancer.gov/default.asp

Google 8 Search Find Check AutoFill Sign In



National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov

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NCI Best Practices

Biospecimen Research Network

Related Initiatives

Resources

PATIENT
CORNER
Learn more



2009 BIOSPECIMEN RESEARCH
NETWORK SYMPOSIUM
March 16-18, 2009

OUR MISSION: The OBBR's mission is to ensure that human specimens available for cancer research are of the highest quality.

The OBBR is responsible for developing a common biorepository infrastructure that promotes resource sharing and team science, in order to facilitate multi-institutional, high throughput genomic and proteomic studies.

[Learn more](#)

OBBR Quick Links



OBRR
Toolbox



Podcast



Funding
Opps

- ▶ [caBIG™ Tools](#)
- ▶ [Human Specimens for Research](#)
- ▶ [The Specimen Resource Locator](#)
- ▶ [Biospecimen Research Database](#)
- ▶ [Providing Your Tissue for Research](#)
- ▶ [NCI Best Practices for](#)



best practices

[Learn more](#)

In Focus

Advancing Cancer Research Through Biospecimen Science

Human biospecimens are the foundation of the translational research that will transform patient care. The 2009 BRN Symposium: Advancing Cancer Research Through Biospecimen Science will focus on the significant impact of pre-analytical biospecimen variables on cancer research and molecular medicine. Please visit the [BRN Symposium](#) for additional information.

The Ethical Use of Pediatric Biospecimens in Research

This one-day workshop addressed the ethical issues involved in the storage and use of pediatric biospecimens in research. Topics included whether



OBBR

Office of Biorepositories
and Biospecimen Research

Research & Policy Initiatives in NCI's Office of Biorepositories & Biospecimen Research

Translational Research Interest Group

December 10, 2009

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Deputy Director

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